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EXAMINER	
LY, CHEYNE D	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 01/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/976,054	CHEIKH ET AL.	
	Examiner	Art Unit	
	Cheyne D Ly	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 12-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 12-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Search Results*.

DETAILED ACTION

1. In view of the Appeal Brief filed on July 23, 2004, PROSECUTION IS HEREBY REOPENED. New grounds of rejections are set forth below.

2. The finality of the instant Office Action has been withdrawn.

3. To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

4. If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

5. Applicant's arguments presented in said Appeal Brief have been addressed below. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

6. Claims 1 and 12-19, SEQ ID NO. 5, are examined on the merits.

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 18, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 1 and 18, line 2, recite the limitation of "fragment thereof" which causes said claim to be vague and indefinite because the metes and bound said limitation as defined by the specification (page 36-38) are not clear. For example, pages 36, lines 11 –14, defines "fragment nucleic acid molecules may encode significant portions(s)" wherein "significant" is a relative term. The specification is not clear as what criteria are being used to determine a portion is "significant" or not. Further, the specification discloses "the fragments may comprise smaller oligonucleotides (having...to about 30 nucleotide residues)." The specification is not clear whether the length limitation in parenthesis controls the lower sized or whether fragments may merely be "smaller oligonucleotides" then those which encode significant portion(s) from line 11. Claim 19 is rejected for being dependent from claim 18.

LACK OF UTILITY UNDER 35 U.S.C. § 101

10. The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

11. The examiner is using the following definitions in evaluating the claims for utility.

> "Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

12. Claims 1 and 12-19 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

13. The critical limitation of claims 1 and 12-19 is the elected polynucleotide SEQ ID NO: 5 that encodes a maize or a soybean adenine phosphoribosyl transferase. It is noted that the limitation of adenine phosphoribosyl transferase has been reasonably interpreted as the claim nucleic acid encoding a protein having adenine phosphoribosyl transferase activity. It is noted that Applicant has identified a sequence that is known in the prior art which has a stated sequence similarity to the claimed sequence. Example 3 (pages 206-207) discloses adenine phosphoribosyl transferase as being identified from the Monsanto EST PhytoSeq database using TBLASTN and GenBank database using BLASTN and BLASTX. A sequence search performed with the sequence of SEQ ID NO: 5 against the PIR_79 and UniProt_02 databases (Results

provided as an attachment) at the USPTO resulted in fragments of the translated protein encoded by the sequence of SEQ ID NO: 5 matching protein sequences that have been characterized as adenine phosphoribosyl transferase in the respective databases. The sequence search results support that the sequence of SEQ ID NO:5 does not comprise the complete open reading frame that encodes for the complete adenine phosphoribosyl transferase protein. Therefore, it has been reasonably interpreted that the claimed sequence of SEQ ID NO:5 encodes fragments of the adenine phosphoribosyl transferase protein, but not the complete adenine phosphoribosyl transferase protein. Therefore, the instant specification does not disclose that SEQ ID NO:5 encodes for the complete adenine phosphoribosyl transferase protein. Further, the instant specification does not describe said fragments with any specific biological activity. The specification does not disclose whether the fragments encoded by the sequence of SEQ ID NO:5 comprise any protein domains that have adenine phosphoribosyl transferase activity. What fragments are responsible for the adenine phosphoribosyl transferase activity? Are the disclosed fragments functional equivalents to the protein encoded by the complete open reading frame that encodes for the complete adenine phosphoribosyl transferase protein? Therefore, one skilled in the art would have reason to doubt that the fragments encoded by the claim SEQ ID NO:5 would have the asserted biological activity of the complete adenine phosphoribosyl transferase enzyme as claimed. The specification does not support that the disclosed fragments encoded by SEQ ID NO:5 have any specific patentably utility.

14. Specific to the disclosed uses (not specified for any particular sequence) mentioned in the specification are generally applicable to many nucleic acids. The specification states that the polynucleotide sequences may be useful in obtaining other nucleic acid molecules such as

promoter sequences, identifying the presences or absence of polymorphisms, and determining expression profiling by probe hybridization (page 55, line 5, to page 83, line 16). The above-mentioned list of desirable utility for the claimed sequence falls short of a readily available utility. These are non-specific uses that are applicable to nucleic acids in general and not particular or specific to the polynucleotide being claimed.

15. The instant specification (page 55, line 5, to page 83, line 16) generically discusses well-known in the art methods for using nucleic acid molecules in identifying promoter sequences, identifying the presences or absence of polymorphisms, or determining expression profiling by probe hybridization. However, the instant specification does not explain why any of the nucleotide molecules disclosed in the specification, or more specifically the elected nucleotide molecules depicted in SEQ ID NO: 5, would in fact be useful in obtaining other nucleic acid molecules such promoter sequences, identifying the presences or absence of polymorphisms, and determining expression profiling by probe hybridization.

16. Applicant further asserts that the polynucleotide sequences may be used to isolate promoters of cell enhanced, cell specific, tissue enhanced, tissue specific, developmentally or environmentally regulated expression profiles (page 57). The instant specification does not provide any disclosure which supports that the nucleic acid molecule depicted in SEQ ID NO: 5 is tissue or cell-type specific, or developmentally or environmentally regulated. It is noted that the specification discloses that the claimed nucleic acid molecule has been isolated from the cDNA library LIB3061 (page 169 and page 208, Table A*). There is no disclosure which supports that LIB3061 has been processed to cause the LIB3061 cDNA library to be cell enhanced, cell specific, tissue enhanced, tissue specific, developmentally or environmentally

regulated expression profiles for the asserted utility. Therefore, the lack of specificity of LIB3061 from which the sequence SEQ ID NO. 5 has been isolated supports that the asserted utilities cited above are neither substantial nor specific as required under 35 U.S.C. § 101.

CLAIMS REJECTED UNDER U.S.C. §112, FIRST PARAGRAPH

17. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

LACK OF ENABLEMENT

18. Claims 1 and 12-19 are rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed sequence. For a sequence putatively assigned a biological function, even if correct, does not appear to be defined as to what use it is to be applied to. The significance of the sequence is undefined, further rendering it indiscernible how someone of skill in the art would use such an entity.

19. The claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above (refer to 35 U.S.C. § 101 rejection), one skilled in the art would not know how to use the claimed invention.

RESPONSE TO ARGUMENTS

20. It is noted that the lack of enablement rejection directed to claims 1, 18, and 19 in the previous Office Action, mailed May 05, 2003 (pages 3-5), has been withdrawn. Therefore, Applicant's arguments presented on pages 11-17 are moot. The basis for the instant lack of

enablement rejection is that Applicant has not disclosed how to use the invention due to the lack of a specific and substantial utility as discussed above.

LACK OF WRITTEN DESCRIPTION

21. Claims 1 and 12-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

22. The specification discloses the nucleic acid sequence as depicted by SEQ ID NO: 5 encoding fragments of adenine phosphoribosyl transferase. Claims 1 and 12-19 encompass "complements thereof" of SEQ ID NO:5, nucleic acid molecules that encode adenine phosphoribosyl transferases, or sequences having sequence identity within a specified percentage range. With the exception of SEQ ID NO: 5 and the encoding fragments of adenine phosphoribosyl transferase, the sequences as encompassed by the full breadth of claims 1 and 12-19 do not meet the written description provision of 35 USC 112, first paragraph. The instant specification has generically described complements but without any written description for any of them. Therefore, the specification provides insufficient written description to support the genus encompassed by the claim.

> Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

23. With the exception of SEQ ID NO: 5 and the encoding fragments of adenine phosphoribosyl transferase, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

> University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that: ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In *re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

24. Therefore, only SEQ ID NO: 5 and the encoding fragments of adenine phosphoribosyl transferase, but not the full breadth of the claims 1 and 12-19 meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.).

RESPONSE TO ARGUMENTS

25. Applicants argue that the specification provides an adequate written description basis for the claimed invention because the specification demonstrates to one skilled in the art that Applicants were in possession of the claimed genera of nucleic acid molecules. Further, Applicants argue that Applicants have described the claimed invention because Applicants have disclosed the common structural features. Applicants' arguments have been fully considered and found to be unpersuasive.

26. The instant specification discloses the sequence of SEQ ID NO: 5 corresponding to a short fragment of a cDNA which Applicants assert to encode a species of adenine phosphoribosyl transferases. The instant specification discloses that the claimed sequence of SEQ ID NO:5 comprising a significant amount of unknown residues, is 73% identity (Table A*) to an adenine phosphoribosyl transferase. The instant specification does not identify the open reading frame of the claimed sequence which encodes the asserted adenine phosphoribosyl transferase. The instant specification does not disclose what function or activity is encoded by the sequence of SEQ ID NO: 5 that supports that the claimed sequence encodes a protein similar to an adenine phosphoribosyl transferase. Further, the disclose sequence contains a high number of residues which have been indicated by Applicants as being "unknown." As cited above, it would have been well known that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases. In the absence of factual evidence characterizing the structural and functional components of the biomolecule to support the assertion that the claimed sequence encodes an adenine phosphoribosyl transferase, the effects of these changes are largely unpredictable as to which ones will have a significant

effect and which ones will be silent mutations having no effect. One of skill in the art would not be able to ascertain that the sequence of SEQ ID NO:5 encodes an adenine phosphoribosyl transferase, or any variants by homology to adenine phosphoribosyl transferase. Therefore, the specification provides insufficient written description to support the genus encompassed by the claims.

27. Specific to the argument directed to the term "comprising" being used in the claims, the written description requirement, under 35 U.S.C. 112, first paragraph, is for the specification to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner has provided adequate reasoning and support that one of skill in the art would not be able to ascertain that the sequence of SEQ ID NO:5 encodes an adenine phosphoribosyl transferase, or any variants by homology to adenine phosphoribosyl transferase. Therefore, the recitation of the term "comprising" in the claims does not change the fact Applicants do not have possession of the claimed invention as recited by the instant claims.

28. Specific to Applicants' argument that the specification reflects Applicants' possession of the claimed invention because Applicants have provided the nucleotide sequences required by the claims such as SEQ ID NO:5, joining sequences via a vector, and sequences which hybridize to the claim sequence under specific conditions. The instant specification does not provide adequate written description basis support for the claims as directed to the sequence of SEQ ID NO:5 which encodes an adenine phosphoribosyl transferase, or any variants by homology to adenine phosphoribosyl transferase.

29. Specific to Applicants' argument directed to separately patentable claims, claims 1 and 12-19 are rejected because the instant specification does not provide adequate written basis support for said claims as directed to the limitation of a nucleic acid molecule that encodes an adenine phosphoribosyl transferase, or variants to the sequences of SEQ ID NO:5 having sequence identity within a specified percentage range.

CLAIM REJECTIONS - 35 USC § 102

30. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

31. Claims 1 and 12-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Moffat et al. (1992).

32. Moffat et al. discloses a complete cDNA for adenine phosphoribosyltransferase from *Arabidopsis thaliana* (Abstract etc.).

33. Moffat et al. discloses the adenine phosphoribosyltransferase comprising a fragment described by the amino acid sequence DP wherein a nucleotide sequence (GATCCC, positions 39-44) complements a nucleic acid sequence at 211-216 positions of SEQ ID NO:5 (page 658), as in instant claims 1 and 18.

34. It is noted that the instant specification defines the limitation as "the 'complement' of another nucleic acid molecule if they exhibit complete complementarity." As used herein, molecules are said to exhibit 'complete complementarity' when every nucleotide of one of the molecules is complementary to a nucleotide of the other. Consistent with the definition of

"complement" (pages 37-38), the Moffat et al. molecule exhibits 'complete complementarity' to a nucleotide of SEQ ID NO:5, as in instant claims 12-19.

35. Claims 1 and 12-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by The Sigma Catalog (1990).

36. The Sigma Catalog discloses a substantially purified nucleic acid molecule "AAAAAA" (page 776, Product number: 0 4628, $d(pA)_6$) which encodes two amino acids. The two amino acids has been reasonably interpreted as encoding a "fragment thereof" of a molecule encoded by the sequence of SEQ ID NO: 5, as in instant claims 1 and 18. Due to the vague and indefinite issue directed to the limitation of "fragment thereof" discussed above, the citation from the Sigma Catalog is consistent with the limitation of "fragment thereof" as defined in the instant specification (page 36).

37. The nucleic acid molecule cited above has been reasonably interpreted as the "first nucleic acid molecule comprises a nucleic acid sequence of SEQ ID NO:5", as in instant claim 19.

38. The Sigma Catalog discloses a substantially purified nucleic acid molecule "AAAA" (page 776, Product number: 0 4378, $d(pA)_4$) which is a complement of SEQ ID NO. 5 at position 24-27. It is noted that the instant specification defines the limitation as "the 'complement' of another nucleic acid molecule if they exhibit complete complementarity." As used herein, molecules are said to exhibit 'complete complementarity' when every nucleotide of one of the molecules is complementary to a nucleotide of the other. Consistent with the definition of

"complement" (pages 37-38), the Sigma Catalog molecule exhibits 'complete complementarity' to a nucleotide of SEQ ID NO:5, as in instant claims 12-19.

CONCLUSION

39. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

40. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

41. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

42. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

43. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

C. Dune Ly
12/27/04

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